



PATENT

New Attorney Docket No. 144009.00200

Old Attorney Docket No. 031672.0005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Wm.A. Knaus & R.D. Marks)
U.S. Appl. No.: 09/822,261) Group Art Unit: 3626
Filing Date: April 2, 2001) Examiner: Lena Najarian
Title: BROADBAND COMPUTER-BASED NETWORKED SYSTEMS
FOR CONTROL AND MANAGEMENT OF MEDICAL RECORDS

MAIL STOP - AMENDMENT

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. §1.131

We, William A. Knaus with a residence address at 1929 Lewis Mountain Road, Charlottesville, VA 22903, and Richard D. Marks with a residence at 6004 Balsam Drive, McLean, VA 22101, are co-inventors of the invention disclosed and claimed in the above-captioned patent application.

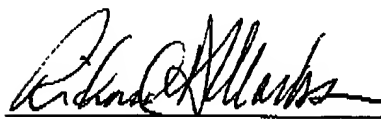
Prior to December 6, 1999, we conceived and reduced to practice the systems and methods according to the claims of the instant patent application, at least to the extent that such systems and methods are disclosed in U.S. Patent Application No. 09/908,524 (Snowden), U.S. Provisional Application No. 60/169,065 (the Snowden Provisional), U.S. Patent Application No. 09/776,673 (Malik), and U.S. Provisional Application No. 60/60/200,091 (the Malik Provisional) (collectively the "Cited References"). Accordingly, Snowden, Malik, the Snowden Provisional and the Malik Provisional cannot be considered to be prior art to our claimed invention.

In support of this Declaration, attached hereto is a document that was prepared by us prior to December 6, 1999 ("Exhibit A"). As clearly established by this document, we conceived and reduced to practice the systems and methods according to the claims of the instant patent application, at least to the extent that such systems and methods are disclosed in the Cited References.

Please note that Exhibit A is being provided here in redacted form. The material redacted contains personal information of a select few people who received this document in confidence. Although the redactions are not proprietary, we do not wish to place personal information into the public record. If the Examiner would like to review the entire document, we would be pleased to allow the Examiner to review an unredacted copy at a personal interview.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above identified application or any patent issued thereon.

Name: William A. Knaus Date: August __, 2005



Name: Richard D. Marks Date: August 23, 2005

Attached: Exhibit A



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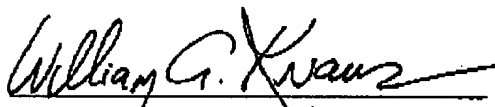
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 Date: August 25, 2005
Name: William A. Knaus

_____ Date: August __, 2005
Name: Richard D. Marks

Attached: Exhibit A

EXHIBIT A

"MANAGING THE
INFORMATION SO
YOU AND YOUR
DOCTOR CAN
MANAGE THE
CARE"

Redacted

Redacted

Redacted

THE STRATEGIC AIM

Create a new "trusted agent" for a consumer focused, clinician sanctioned, Internet based healthcare information, decision support, and treatment recommendation utility.

THE BUSINESS OPPORTUNITY

Enable consumers to use the Internet as their "preferred first stop" for obtaining all non-emergency medical care advice and guidance. Prior to visiting a clinician or a clinic, the person would transmit their medical data and problem or inquiry to the "trusted agent" via the Web. The trusted agent would search a variety of objective and valid sources to obtain comprehensive state of the art individualized medical information, prognoses, and a comprehensive assessment of treatment alternatives and likely outcomes. The structure of this information would enable individual consumers to interpret the findings and then interact with clinicians and health care delivery systems as informed consumers and prudent purchasers of specific services. The nature and efficiency of the patient-clinician contact would be improved by concentrating communication on the patient's values and preferences for specific alternatives. Considerations of cost, convenience, and quality (practitioner performance, reputation, etc.) could also have a larger role in treatment choices

SPECIFIC OBJECTIVES AND CORE COMPETANCES

1. Develop and disseminate new conceptual and technical approaches to;
 - a) The structure and organization of medical data and information content,
 - b) the process of information search and inquiry response
 - c) the presentation and graphical user interface for healthcare data
2. Continually evaluate the usefulness and impact of these approaches on the quality of healthcare delivery with the results supporting improvements in content and presentation.

BRIEF BACKGROUND AND RATIONALE

It is widely acknowledged that the Internet will change the way we think about and the way we conduct many aspects of our economy and our society. The most immediate and profound changes have been in commerce where the marketing and purchase of a wide variety of goods and services are being transferred to the Internet. Overtime, it is envisioned that more and more services will have a part of their market in Internet space. The Internet is also about information and control. As Andrew Shapiro writes in his book, *The Control Revolution*, the Internet will reduce and in some cases eliminate intermediaries by bringing consumer and supplier in direct contact with identical information. As a heavily information based service industry healthcare will also be affected and changed by the Internet but there are some unique considerations.

Historical and Ongoing Obstacles to IT in Healthcare

While medical care is an information based service industry, it is very far behind other service sectors in its use of information technology. Much of this resistance, in my experience, comes from the conservative nature of the profession and its practitioners. During this century medicine has largely functioned as a cottage industry with the medical practitioner as the gatekeeper for medical information, treatment recommendations, and provision of services. Approaches to health care information technology have been slow because practitioners and systems have demanded individual customized approaches to data acquisition, handling and transfer and have actively resisted standardization because it threatens their control. Healthcare IT companies have attempted to overcome this resistance by developing proprietary enterprise wide solutions that can never be truly enterprise wide because of the lack of standards and the non-integrated nature of most "integrated" health care systems. There is no industry giant in healthcare IT with the market divided among 12 or so primary proprietary enterprise type systems (Cerner, HBOC, Eclipsys, SMS, etc.) and hundreds if not thousands of "best of breed" isolated management or decision support systems (HCIA, Medical Logic, MeCon, APACHE, etc.) The government has never used its large market presence to promote either integration or standardization. Current financial incentives do not directly reward investment or use of IT services.

The result is substantial inefficiency in the storage, retrieval, and availability of data. The consequences are a large number of medical mistakes, great variations in the choices of therapies and an increasing lack of trust in the ability of the profession to manage and make appropriate use of ongoing scientific discoveries.

A New Model-The Consumer as integrator and "standard bearer" for healthcare data

My approach would use the power of the Internet to develop a new model for healthcare information dissemination and interpretation. Rather than attempting to convince clinicians to adopt state of the art information retrieval or decision support systems or for health care systems to coordinate thousands of disparate islands of data, the individual patient would be the main repository their medical information, would be able to initially access its clinical implications, and then "carry" the results with them to all medical encounters regardless of location. This would effectively eliminate the

intermediary, the "IT poor practitioner or the IT dysfunctional health system" as the repository of healthcare data and knowledge. In effect, the medical care system would need have "read only" information systems. They would be capable of receiving individual patient data and recommendations and then updating it with current data at the end of the encounter and then return it to the patient.

The simple but powerful rationale behind this effort is that all healthcare transactions are centered on patients or patient data. They are the most efficient way to integrate the system. The patient, members of their family, or trusted advocates are also the most interested in insuring that their medical information be accurate and the advice given appropriate. Because of the focused nature of their problem they also will be able to devote the time to research the implications of their findings. The incentives for them are more control over healthcare decision and greater assurance of quality care, two highly desired outcomes for individuals.

Individuals therefore would be the main customers for this service. The revenue model could be a yearly or monthly subscription based or pay as you go service akin to Internet access or cable use. This approach to revenue would also insure that the "trusted agent" would remain an unbiased and independent provider of objective data that would be in the patient's best interest.

Because most services would still be provided through the practitioner, the information and data provided by the trusted agent would have to be respected and acknowledged by the clinician. Appropriate incentives and respect would need to be created in order for this to occur. I admit this is the least well worked out part of this proposal.

THE UNDERLYING ASSUMPTIONS I AM MAKING (In no particular order)

1. The Internet will become the primary source of information for both the clinician and the consumer
2. There are currently no trusted agent brokers for clinician or patient specific electronic health care information or queries.
3. Medical therapy is going to become more and more individualized
4. Medical services will be more consumer driven
5. The amount of information available when considering a medical decision is going to grow.
6. The demands of privacy (and the draft HIPPA regulations) will increasingly stress data transfer security and encourage "ownership" and dissemination of this detailed medical data to the individual.
7. Cost and convenience concerns will make the location of care more flexible and price, convenience, and brand name or provider reputation more important

HOW THIS IS DIFFERENT

As the mad scramble for health care portals continue, there is a notable lack of content-development. More importantly, there is an explicit assumption that the practitioner is the disseminator of all recommendations or interpretation and that 'systems' not individuals will control the data. Even the most prestigious and well-regarded emerging Internet sites provide generic or expert based ("ask a doc") advice oriented around condition or problem not individual. As the above assumptions indicate I am proposing that this approach is wrong. Healthcare will change and healthcare data and recommendations will become much more "retail"-- accessible to all, not just practitioners and institutions- and that the provision of medical services (as opposed to information) will increasingly become a commodity.

HOW THIS WOULD WORK-PROSTATE CANCER AS AN EXAMPLE

A man is recently diagnosed with prostate cancer. He has the results from his physical and laboratory tests. He goes to the "trusted agent" and structures a free text inquiry about his prognosis and treatment alternatives. The tool searches the medical literature, finds either the necessary applicable data or, if available, the algorithms that permit the clinician to take a patient's medical data, age, family history, PSA level, Gleason Score (if a biopsy was done) and provide a very detailed estimation of prognosis under the three dominant treatment options; surgery, radiation therapy, and watchful waiting.

Initially this web based approach might program these algorithms into the instrument to enable the individual to have this data so they would understand their situation and what options were available and appropriate. Overtime, as Bill Detmer, has taught me, the inquires would not have to rely on pre-programmed algorithms but could be more flexible with inquiries addressed from raw data. The presentation would be done both with a combination of specifically designed and tested web-based graphic and textual patient education material that would enable the person to drill down into the specifics of the data and the recommendations. They could obtain additional details on what surgical options means in terms of description of the procedure. They could investigate how their personal preferences and values might influence the decision to have surgery.

I can also envision linking such data to specific medical resources requested by the patient i.e. the local urologist for data on the number of surgeries he had performed and his outcomes. Soon, as Andrew Heller has indicated, when broadband is used, the system could be even more interactive. It could monitor and direct care services directly from the patient's home-say monitoring the daily volume and nature or urinary flow and functional status with the presumption that the preferred site of most care and virtually all of patient-physician communication in the future will be the patient's home or office.

NEXT STEPS

1. Reaction to the overall concept and willingness to remain in the dialogue (anyone can drop out with no hard feelings)
2. Discussion of the concept of "trusted agent" as an operating business concept
My thinking here is that the managed care companies were supposed to do this but they really blew any chance by focusing on short term profits without much investment in information technology or quality of consumer services. The current backlash against managed care, however, and the non-physician gatekeeper provides an excellent opportunity to position this new entity. The slogan might be something like "Managing Information so that you and your doctor can Manage the Care" 5 10
3. Are there 2 separate but related business here i.e. a personal medical data management company and a medical information and recommendation entity?
4. What do we do about the docs? While I do not believe they are our main customer they must be satisfied and accepting of the data and information otherwise they could sabotage the effort. 15
5. How to get started- Given all the talent and resources briefly outlined above there are a lot of potential options. If we get through this initial conceptual phase, I will be glad to outline them with your help.

That's it.



ALTERNATIVE TO PTO/SB/08a/b (06-03)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/822,261
				Filing Date	April 2, 2001
				First Named Inventor	William A. KNAUS et al.
				Art Unit	3626
				Examiner Name	Lena Najarian
Sheet	1	of	1	Attorney Docket Number	144009.00200

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1.	William A. KNAUS and Richard D. MARKS, "Managing the Information so You and Your Doctor Can Manage the Care," pp. 1-7, (Nov. 1999) (redacted).	

Examiner Signature		Date Considered	
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